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Attorneys for Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB

DECLARATION OF ROBERT HARDI, M.D.

1. I, Robert Hardi, M.D. have been retained by Sughrue Mion, PLLC (counsel for Hanmi USA Inc., et al) to provide expert testimony in the above captioned action. I reserve the

right to supplement this declaration as additional information is made available to me, including information provided by AstraZeneca in the present action and evidence at trial. I may also provide testimony in response to any expert opinions offered by AstraZeneca.

I. Background

2. I received a Medical Degree, Summa cum Laude, in 1972 from Semmelweis University Medical School, Budapest, Hungary. I did post graduate training in Biochemistry and Genetics and worked as Assistant Professor of Genetics at Eotvos Lorand University of Sciences in Budapest, Hungary. I also did a year of post doctoral Fellowship in the Department of Pharmacology of SUNY Buffalo, in conjunction with the Department of Virology of Roswell Park Memorial Institute. I did my training in Internal Medicine at Semmelweis University Medical School, ST. Bonifatius Hospital in Lingen, Germany, Hannover University Medical School in Germany and The University of New Mexico Medical School in Albuquerque, New Mexico. Following my residency, I completed a Hematology-Oncology Fellowship at the University of New Mexico Medical School, Albuquerque, New Mexico in 1982 and a GI Fellowship at Cornell University Medical College, New York, New York in 1984.

3. I have been a Diplomate of the American Board of Internal Medicine since 1983, and specifically with the Gastroenterology division of American Board of Internal Medicine since 1985. I have been a Certified Physician Investigator since 2005.

4. I have been in the private practice of Gastroenterology and Internal Medicine in Washington, DC since 1984. I joined Metropolitan Gastroenterology Group in early 1996.

5. I am currently the Medical Director and Principal Investigator of Chevy Chase Clinical Research as well as a treating physician with Metropolitan Gastroenterology Group, PC, and have been so since 1996. As Medical Director, my general responsibilities include oversight of all research activities of the group.

6. I have been the Principal Investigator on more than 250 gastroenterology clinical trials encompassing all phases and all areas of Gastroenterology, including trials of acid reducing compounds.

7. I treat patients having a variety of gastroenterological conditions and diseases including but not limited to, gastric ulcer, duodenal ulcer, reflux esophagitis and gastritis and duodenitis as well as non ulcer dyspepsia, adverse effects stemming from use of non-steroidal anti-inflammatory drugs (NSAIDs), gastro-esophageal reflux disease (GERD), gastrinomas, Zollinger-Ellison syndrome, upper gastrointestinal bleeding, and helicobacter infections.

8. In addition to practicing with the Metropolitan Gastroenterology Group, I am a staff physician at Sibley Memorial in Washington D.C. and Suburban Hospital in Bethesda, Maryland.

9. I am a Clinical Assistant Professor of Medicine at Georgetown University Medical School and Clinical Associate Professor of Medicine at George Washington University Medical School.

10. I am a member of American Society of Gastrointestinal Endoscopy, American Gastroenterological Association- Fellow, American College of Gastroenterology, Academy of Pharmaceutical Physicians and Investigators, International Society for Travel Medicine and the Crohn’s and Colitis Foundation of America.

11. I have presented lectures on Inflammatory Bowel Diseases and speak on the management of acid related diseases as a member of Takeda Pharmaceuticals' Speaker Bureau. I have co-authored 16 publications on Inflammatory Bowel Diseases, Pharmacology and procedural sedation.

12. A copy of my c*urriculum vitae* is attached as Exhibit A.

13. Based on my experience and education as set above, including over 28 years in working in the field of gastroenterology, I provide the following views regarding U.S. Patent No. 5,714,504 and U.S. Patent No. 5,877,192.

II. Scope of Review

14. I have been asked to provide comments on specific claim terms in U.S. Patent No. 5,714,504 and U.S. Patent No. 5,877,192, and have done so below. In particular, I have considered certain aspects of claims 6 and 7 of U.S. Patent No. 5,714,504, and I have considered certain aspects of claims 1 and 2 of U.S. Patent No. 5,877,192. My comments are below.

15. I have not been asked to comment on any claim terms other than those discussed below, nor have I been asked to consider any other issues in this case.

III. Discussion

A. Credentials of a Person Of Ordinary Skill In The Art

16. I have reviewed U.S. Patent No. 5,714,504 ("the '504 Patent") which is based on U.S. Patent Application No. 376,512 filed January 23, 1995 ("the '512 application"), and which references on the cover page two prior applications filed in 1994 and 1993. I have also reviewed the '512 application and Patent Office prosecution history of the '504 patent. I have

also reviewed U.S. Patent No. 5,877,192 ("the '192 Patent") which is based on U.S. Patent Application No. 833,962 filed April 11, 1997, and which references on the cover page the prior '504 patent and its predecessor applications. I have also reviewed the '962 application and the Patent Office prosecution history of the '192 patent.

17. The '504 and '192 patents can be considered multi-disciplinary to some extent, because they discuss certain chemistry, synthetic process and stereochemistry concepts on the one hand, while also discussing the practical utilities of the formulations, modes of administration and biological effects on the other hand. Clearly, these patents are written not for just a single person, and describe concepts and technologies requiring knowledge of different professionals with largely non-overlapping backgrounds -- such as chemists and medical practitioners. I am providing views on the claim terms from the latter's standpoint, and understand that other experts who may opine on chemistry issues (such as optical purity to name one example) would describe the qualifications and skill set of a person of ordinary skill in the art in a different but complementary way than I do here, based on the requirements of the patents.

18. It is my opinion that, at the time of the patent filings in the 1993-1997 time frame, one of ordinary skill in the art of diagnosing and treating gastroenterological diseases and conditions discussed in the patents would be a physician, such as a gastroenterologist, with a degree in medicine and post-graduate clinical training and experience in examining patients and working knowledge of the etiology and pathology of the spectra of diseases and conditions affecting the gastrointestinal tract as well as a knowledge of available medications, treatment regimens, therapies and procedures. Another example would be a primary care physician or

internist, who would diagnose and treat routine gastrointestinal conditions but who would usually refer a patient to a gastroenterologist or other specialist in more complicated cases to obtain definite diagnosis, guidance in treatment and follow up. Such a person would typically have 3-5 years of working experience treating patients for gastrointestinal disorders.

19. Based on my education and experience over the past 39 years, I am able to comment on the knowledge of such a person at the relevant time. The qualifications and skill set of such a person of ordinary skill in the art in 1993, 1995 or 1997 would have been the same.

B. "Administration" And "Administering To A Mammal In Need Of Treatment" In The Context Of Practicing The Methods Of The '504 And '192 Patent

'504 Patent – Claims 6 and 7

20. Claim 6 of the '504 patent reads as follows:

> A ***method of inhibiting gastric acid secretion*** comprising the oral ***administration of a pharmaceutical formulation comprising a therapeutically effective amount*** of a pure solid state alkaline salt of the (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and a pharmaceutically acceptable carrier.

I have focused on the bold face language in my following comments.

21. Claim 7 of the '504 patent reads as follows.

> A ***method for the treatment of gastrointestinal inflammatory disease*** comprising the oral ***administration to a mammal including man in need of such treatment*** of a pharmaceutical formulation comprising a ***therapeutically effective amount*** of a pure solid state alkaline salt of the (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and a pharmaceutically acceptable carrier.

I have focused on the bold face language in my following comments.

22. I have been asked to consider the meaning of "administration of" in claim 6 and "administration to" in claim 7, in the context of those claims from the standpoint of one of

ordinary skill in the art in the mid-1990's. I am informed that Hanmi asserts that "administration" in each of these claims means: "the prescription by a physician or other licensed healthcare professional, dispensing and ingestion." Given the precise context of these claims in light of the manner in which such methods are actually carried out in day-to-day practice, in my judgment Hanmi's interpretation would be consistent with the views of a person of ordinary skill in the art in the mid-1990's. The reasons in support of this conclusion are set forth below.

23. I have been asked to assume that AstraZeneca's Nexium® is a pharmaceutical formulation within the scope of claims 6 and 7 (and also claims 1 and 2 of the '192 patent) and is the only commercially available product meeting that description. In the United States, Nexium® is available only by prescription. I often prescribe Nexium® in the course of my gastroenterology practice.

24. The context of the claim language in which the "administration" term appears makes clear that the involvement of a physician or other licensed healthcare professional (I will use "physician" for short) is required. This is because the claims require administration of a therapeutically effective amount of the pharmaceutical formulation and because in practice Nexium® is available only by prescription. One of ordinary skill would also immediately appreciate that only a physician is capable of determining what amount would be therapeutically effective.

25. Claim 7 additionally requires that the mammal that is the subject of administration be "in need of such treatment." One of ordinary skill reading this language would immediately recognize that the diagnosis of a physician is required, since only those individuals can capably

determine that a subject 1) has gastrointestinal inflammatory disease (through diagnosis), and 2) requires treatment with the claimed formulation, in addition to determining the "therapeutically effective amount" as discussed above.

26. Although not explicitly stated in claims in 6 and 7, one of ordinary skill in the art in the mid-1990's would have understood the term "administration" to also require the physician to prescribe the drug product to the subject being treated. In practice in the United States, such subjects are typically human patients and I will refer to patients for short. From the real world perspective of the person of ordinary skill in the art, prescription medications are federally regulated and can only be dispensed by entities licensed to do so, e.g., pharmacies, managed healthcare organizations, etc. On occasion physicians can and sometimes do prescribe and dispense "sample" prescription medications, that were provided by manufacturers' drug representatives, directly to patients during an office visit.

27. To complete the "administration" required by claims 6 and 7, the patient would need to orally ingest the prescribed drug product.

28. The '504 patent specification is consistent with my comments above concerning the meaning of "administration" in claims 6 and 7 and "mammal in need of treatment" in claim 7. For example, I have quoted below some relevant portions of the patent specification that support this conclusion.

> Typical daily dose of the active compound will depend on various factors … such as … ***individual requirement of each patient,*** the ***route of administration*** and … (column 6, lines 21-25);
>
> It is desirable to obtain compounds with … which will give an improved ***therapeutic*** profile … (column 1, lines 50-53);

> The compounds of the invention may be used for inhibiting gastric acid secretion in mammals and man. In a more general sense, the compounds of the invention may be used for the ***treatment*** of gastric-acid related ***diseases*** and gastrointestinal inflammatory ***diseases*** in mammals and man … (column 2, lines 17-23);
>
> ...compounds may be used for ***treatment*** of other gastrointestinal disorders where gastric antisecretory is desirable, e.g., ***patients*** on NSAID therapy, in ***patients*** with gastrinomas, and in ***patients*** with acute upper gastrointestinal bleeding ... (column 2, lines 23-27);
>
> They may also be used in ***patients in intensive care*** situations and ***pre- and post-operatively*** … for ***treatment*** or ***prophylaxis*** of inflammatory conditions. Conditions that may be specifically mentioned for ***treatment*** are rheumatoid arthritis and gout … also useful in the ***treatment*** of psoriasis as well as ... Helicobacter infections (column 2, lines 17-37.) (emphases added).

Based on these statements, one of ordinary skill would understand that the pharmaceutical formulations of the '504 patent are intended for 1) clinical therapeutic use, 2) "administration" occurs in the context of methods where the need for inhibiting gastric acid secretion has been recognized, and 3) therapeutically effective amounts will vary from subject to subject based on multiple factors.

29. In the context of claims 6 and 7, the physician's determination of a therapeutically effective amount will vary patient by patient. This is made clear by the '504 patent (column 6, lines 21-25). Such a determination cannot be made without an assessment as to whether a patient is in need of treatment as claimed.

The '192 Patent – Claims 1 and 2

30. Claim 1 reads as follows:

> A ***method for treatment of gastric acid related diseases by inhibition of gastric acid secretion*** comprising ***administering to a mammal in need of treatment a therapeutically effective amount*** of a proton pump inhibitor consisting essentially of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or a pharmaceutically acceptable

> salt thereof, so as to effect decreased interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases.

I have focused on the bold face language in my following comments.

31. Claim 2 reads as follows:

> ***A method for treatment of gastric acid related diseases by inhibition of gastric acid secretion*** comprising ***administering to a mammal in need of treatment a therapeutically effective amount*** of a proton pump inhibitor consisting essentially of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or a pharmaceutically acceptable salt thereof, so as to effect an increased average plasma levels (AUC) per dosage unit.

I have focused on the bold face language in my following comments.

32. I have been asked to consider the meaning of "administering to a mammal in need of treatment" in the context of those claims from the standpoint of one of ordinary skill in the art in the mid-1990's. I am informed that Hanmi asserts that "administering to a mammal in need of treatment" in each of these claims means: "the prescription by a physician or other licensed healthcare professional, dispensing and delivery by any suitable means." Given the precise context of these claims in light of the manner in which such methods are actually carried out in day-to-day practice, in my judgment Hanmi's interpretation would be consistent with the views of a person of ordinary skill in the art in the mid-1990's. The reasons in support of this conclusion are set forth below.

33. The context of the claim language in which the "administering" phrase appears makes clear that the involvement of a physician is required. This is because the claims require administering a therapeutically effective amount of the pharmaceutical formulation to a mammal in need of treatment and because in practice Nexium® is available only by

prescription. One of ordinary skill would also immediately appreciate that only a physician is capable of determining what amount would be therapeutically effective.

34. Claims 1 and 2 require that the mammal is "in need of such treatment." One of ordinary skill reading this language would immediately recognize that the diagnosis of a physician is required, since only those individuals can capably determine that a subject 1) has a "gastric acid related disease" (through diagnosis), and 2) requires treatment with the claimed formulation, in addition to determining the "therapeutically effective amount" as discussed above.

35. Although not explicitly stated in claims in 1 and 2, one of ordinary skill in the art in the mid-1990's would have understood the term "administering " to also require the physician to prescribe the drug product to the subject being treated. In practice in the United States, such subjects are typically human patients. As I discussed above, from the real world perspective of the person of ordinary skill in the art, prescription medications are federally regulated and can only be dispensed by entities licensed to do so, e.g., pharmacies, managed healthcare organizations, etc., but on occasion a physician will prescribe and dispense "sample" prescription medications directly to patients during an office visit.

36. To complete the "administering to a mammal in need of treatment" required by claims 1 and 2, the patient could be delivered the drug product by any suitable means. While claims 6 and 7 of the '504 patent discussed above specifically require oral ingestion, claims 1 and 2 of the '192 patent allow for oral ingestion, parenteral routes, etc. ('192 patent, column 4, lines 19-24).

37. The '192 patent specification is consistent with my comments above concerning the meaning of "administering to a mammal in need of treatment" in claims 1 and 2. For example, Below, I refer to below some relevant portions of the patent specification that support this conclusion. The '192 patent specification statements confirm that 1) the methods and formulations are intended for clinical therapeutic use, 2) "administering" occurs in the context of methods where the need for inhibiting gastric acid secretion, or treatment of a disease/condition has been recognized, and 3) therapeutically effective amounts will vary from patient to patient based on multiple factors. For example, the '192 patent specification at column 4, lines 25-31:

> "The most suitable route of administration as well as the magnitude of a therapeutic dose of the (-)-enantiomer of omeprazole or a pharmaceutically acceptable salt thereof in any given case will depend on the nature and severity of the diseases to be treated. The dose, and dose frequency, may also vary according to age, body weight, and response of the individual patient.

For further examples, refer to column 2, lines 13-63, column 3, lines 37- 60, column 4, line 60 - column 7, line 17, column 4, lines 31-44.

38. In the context of claims 1 and 2, the physician's determination of a therapeutically effective amount will vary patient by patient. This is made clear by the '192 patent (column 4:25-44). Such a determination cannot be made without an assessment as to whether a patient is in need of treatment as claimed.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 4, 2011

Robert Hardi, M.D.

EXHIBIT A

Robert Hardi, M.D., AGAF, CPI
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SITE AFFILIATIONS

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Metropolitan Gastroenterology Group, PC
2021 K Street NW, Suite T110
Washington, DC 20006

Chevy Chase Endoscopy Center
5530 Wisconsin Ave, Suite 500
Chevy Chase, MD 20815

Endoscopy Center of Washington, DC
2021 K Street NW, Suite T115
Washington, DC 20006

CREDENTIALS

Medical License: D0030771 Maryland
Medical License: MD14559 District of Columbia

2010- Fellow- American Gastroenterological Association
1985 – Present: Diplomate - American Board of Internal Medicine - Gastroenterology
1983 – Present: Diplomate - American Board of Internal Medicine
2005 Certified Physician Investigator

EDUCATION

1972 – 1974	Postdoctoral - Biochemistry,Genetics, Semmelweis University Medical School, Budapest, Hungary
1966 – 1972	MD - Semmelweis University Medical School, Budapest, Hungary
1962 – 1966	Apaczai Gymnasium, Budapest, Hungary

TRAINING

1982 – 1984	GI Fellowship, Cornell University Medical College, New York, New York
1982 – 1982	Senior Resident-Internal Medicine - University of New Mexico Medical School, Albuquerque, New Mexico

1979 – 1982	Hematology-Oncology Fellowship, University of New Mexico Medical School, Albuquerque, New Mexico
1978 – 1979	Residency, Internal Medicine: Medical University of Hannover, Hannover, West Germany
1977 – 1978	Residency, Internal Medicine: St. Bonifatius Hospital, Lingen, West Germany
1976 – 1977	Internship: First Medical Clinic, Semmelweis University Medical School, Budapest, Hungary
1975 – 1976	Post-doctoral Fellowship - State University of New York at Buffalo and Roswell Park Memorial Institute; Department of Medical Viral Oncology, Buffalo, New York

WORK EXPERIENCE

2004 – Present	Physician – Lufthansa Airlines – Washington, DC
1997 – Present	Consultant, Gastroenterologist - World Bank, US Dept. of State
1996 – Present	Principal Investigator and Medical Director- Metropolitan Gastroenterology Group, P.C., Chevy Chase Clinical Research, Chevy Chase, Maryland
1996 – Present	Physician - Metropolitan Gastroenterology Group, P.C. (Private Practice, Gastroenterology & Internal Medicine), Chevy Chase, Maryland & Washington, DC
1996 – Present	Physician - Chevy Chase Endoscopy Center, Chevy Chase, MD
1996 – Present	Physician - Endoscopy Center of Washington, DC, Washington, DC
1990 – Present	Physician - Embassy of the Federal Republic of Germany, Washington, District of Columbia
1984 – 1996	Physician - Private Practice of Gastroenterology, Washington, District of Columbia

ACADEMIC APPOINTMENTS

1992 – Present	Clinical Assistant Professor of Medicine, Georgetown University Medical School, Washington, District of Columbia
1984 – 2011	Assistant Clinical Professor of Medicine, George Washington University Medical School, Washington, District of Columbia
2011-Present	Clinical Associate Professor of Medicine, George Washington University Medical School, Washington,D.C.
1973 – 1975	Assistant Professor of Genetics, Eotvos University of Sciences, Budapest, Hungary

PROFESSIONAL APPOINTMENTS

2011 – Present	Chairman, Research Committee, Capital Digestive Care
2011 – Present	Member, APPI's representative on the Professional Development Committee of the ACRP
1984 – Present	Member, Medical Advisory Committee, CCFA, National Capital
1990 – 2001	Chairman of Gastroenterology, Columbia Hospital for Women, Washington, District of Columbia
1995 – 1998	Board of Directors, Capitol Physicians Network
1994 – 1998	Member, National Board of CCFA
1994 – 1996	Judicial Council, Medical Society of the District of Columbia

1988 – 1994	Chairman, National Capital Area Medical Advisory Committee for CCFA,
1993 – 1992	Vice Chairman, Utilization Review Committee, Sibley Memorial

HOSPTIAL AFFILIATIONS

1992 – Present	Staff Physician, Georgetown University Hospital, Washington, District of Columbia
1984 – Present	Staff Physician, Suburban Hospital, Bethesda, Maryland
1984 – Present	Staff Physician, Sibley Memorial Hospital, Washington, District of Columbia
1984 – Present	Staff Physician, George Washington University Hospital, Washington, District of Columbia
1984 – 2001	Staff Physician, Columbia Hospital for Women, Washington, District of Columbia

MEMBERSHIPS

American Society of Gastrointestinal Endoscopy
American Gastroenterological Association- Fellow
American College of Gastroenterology
American College of Physicians
Academy of Pharmaceutical Physicians and Investigators
International Society for Travel Medicine
Crohn's and Colitis Foundation of America

RESEARCH ACTIVITY

Robert Hardi has been Principal Investigator on more than 250 gastroenterology clinical trials encompassing all phases and all areas of Gastroenterology including polyp prevention, sedation trials and therapeutic device trials.

PUBLICATIONS

1. Hardi R, Hughes RG, Ho YK, Chadha KC, Bardos TJ. Differential Effects of 5-Methylmercapto-2'-Deoxyuridine on the Replication of Herpes Simplex Virus Type 1 in 2 Cell Systems. Antimicrobial Agents and Chemotherapy, Oct 1976 p. 682-686.

2. Balsalazide Is Superior to Mesalamine in the Time to Improvement of Signs and Symptoms of Acute Mild-to-Moderate Ulcerative Colitis; "The American Journal of Gastroenterology", Vol. 97, Number 12, Dec, 2002.

3. Katz S., Novick, J., Hardi R., Rose M., Karlstadt R., Lottes S., Ettinger N. "Efficacy and Safety Profile of Older Patients Using Oral INKP-102 as a Bowel Purgative Prior to Colonoscopy Compared to Visicol". Poster presented at ACG. 2005

4. Hanauer S.B., Sandborn W.J., Kornbluth A., Hardi R., Regalli G., Yeh C. Delayed-release oral mesalamine 4.8 g/day (800mg tablet) versus 2.4 g/day (400mg tablet) for treatment of moderately active ulcerative colitis: combined analysis of two randomized, double-blind, controlled trials. Gastroenterology 2005 Apr; 128(4, Suppl 2): A-74. Abstract 492.

5. Hanauer S.B., Sandborn W.J., Kornbluth A., Hardi R., Regalli G., Yeh C. Delayed-release oral mesalamine 4.8 g/day (800mg tablet) versus 2.4 g/day (400mg tablet) for treatment of moderately active ulcerative colitis: combined efficacy analysis of two randomized, double-blind, controlled trials. Can J Gastroenterology 2005 Sept; 19 (Suppl C): Abstract R.0470.

6. Hanauer S.B,. Sandborn W.J. Kornbluth A., Hardi R., Regalli G., Yeh C. Modified-release oral mesalazine 4.8 g/day (800mg tablet) versus 2.4 g/day (400mg tablet) for treatment of moderately active ulcerative colitis: combined analysis of two randomised, double-blind, controlled trials. Gut 2005 Oct; 54(Suppl VII): A56. Abstract OP-G-236.

7. Hanauer S.B., Sandborn W.J., Kornbluth A., Hardi R., Regalli G., Yeh C. Modified-release oral mesalazine 4.8 g/day (800mg tablet) versus 2.4 g/day (400mg tablet) for treatment of moderately active ulcerative colitis: combined analysis of two randomized, double-blind, controlled trials. Colorectal Dis 2006 Jul; 8 (Suppl 2): Abstract O17.

8. Aue, G., Carroll, N., Kressel, B. R., Hardi, R., Horne III, M. K. Disseminated Intravascular Couagulation in an Ambulatory Young Woman. Journal of Laboratory and Clinical Medicine, Vol.146 #3, Sept 2005 192-196.

9. Gan T.G., Hardi R., Ekman E., Shore N. "Safety of Fospropofol for Minimal-to-Moderate Sedation in Patients Undergoing Minor Surgical Procedures", Poster, Presented at the Society for Ambulatory Anesthesia 23rd Annual Meeting, Miami, May 2008.

10. Pambianco, D., Bray, W., Hardi, R., Kodali, V., Pruitt, R., Shubert, T., Vargo, J., Weinstein, M. L. "A Computer- Assisted Personalized Sedation System To Administer Propofol Versus Standard Of Care Sedation For Colonoscopy And EGD: A 1000 Subject Randomized, Controlled, Multi-center, Pivotal Trial". Presentation DDW 2008.

11. Weinstein ML, Hardi R, Vargo J, Pambianco D: Psychomotor Recovery After Endoscopic Procedures Using a Computer-Assisted Personalized Sedation System to Administer Propofol or Standard of Care Sedation: Implications for Care Efficiency. Poster Abstract. Orlando, Florida. ACG Sept 2008.

12. Abreu MT, von Tirpitz C, Hardi R, et al. "Extracorporeal photopheresis for the treatment of refractory Crohn's disease: results of an open-label pilot study"; Crohn's Disease Photopheresis Study Group. Inflamm Bowel Dis. 2009 Jun; 15(6):829-36

13. Hardi R., Weinstein, M. L., Vargo, J., Pambianco, D. "Correlation of Hypoxia, Clinician Satisfaction (CSSI), Patient Satisfaction (PSSI) and Recovery Time (RT) with Level of Sedation", Poster, Presented at the American Gastroenterology Association, Chicago, June 2009.

14. Daniel J. Pambianco, MD, John J. Vargo, MD, MPH, Ronald E. Pruitt, MD, Robert Hardi, MD, James F. Martin, PhD. "Computer-assisted personalized sedation for upper endoscopy and colonoscopy: a comparative, multicenter randomized study", Gastrointestinal Endoscopy 2010.

15. Update on Colorectal Cancer Screening in the United States Gastro Update 2009.

16. The debate for nonanesthesiologist-administered propofol sedation in endoscopy rages on by Daniel J. Pambianco, Robert Hardi Gastrointestinal Endoscopy (Vol.74, Issue 2).

PRESENTATIONS:

Hardi, R, Mayer, L., Targan, S., Yellin, M., Cardarelli, P., Witte, A., & Das, K. A Phase 1 Open–label, Single-dose, Dose-escalation Study of MDX-1100, a High-affinity, Neutralizing, Fully Human IgG1κ anti-CXCL10 (IP-10) Monoclonal Antibody, in Ulcerative Colitis. DDW 2008, San Diego

ASCEND: Assessing the Safety& Clinical Efficacy of a New Dose of 5-ASA (4.8 /day) (800 mg tablet) Association of ColoProctologists of Great Britain and Ireland; 2006, Newcastle